

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	SEP 26 2001
Publication Date	SEP 27 2001
Certifier	SREESE

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 24, 2001, from 9 a.m. to 3 p.m., on October 25, 2001, from 8 a.m. to 6 p.m., and on October 26, 2001, from 8 a.m. to 3 p.m.

Location: Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Gail Dapolito or Rosanna L. Harvey (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 24, 2001, the committee will meet to discuss long-term followup of participants in gene transfer clinical trials. On October 25, 2001, the committee will discuss vector design, manufacture, and preclinical studies of lentivirus vectors in gene transfer clinical trials. On October 26, 2001, the committee will discuss development of a lentivirus vector gene transfer product for people with human immunodeficiency virus (HIV).

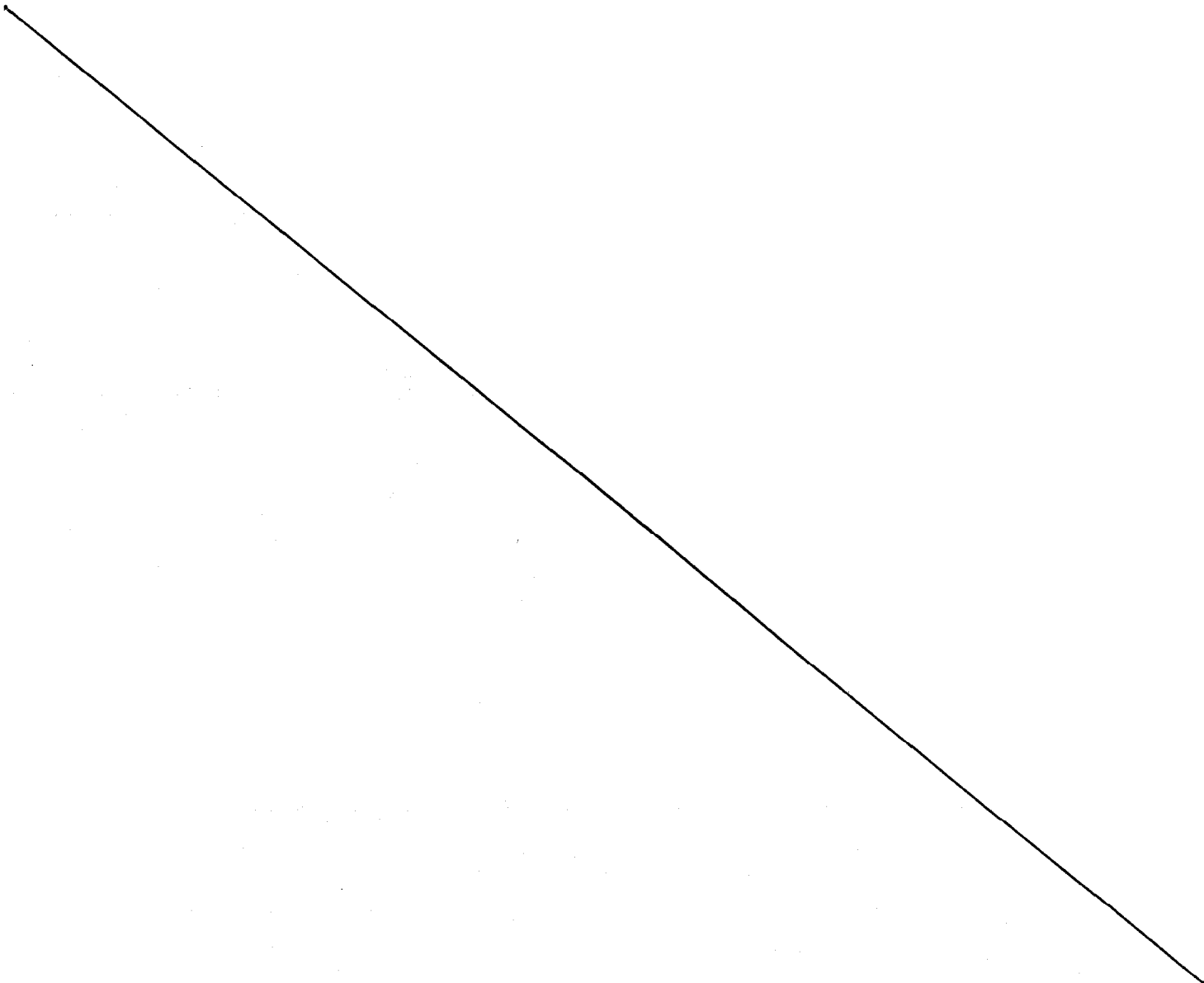
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person
oc01227

3794

NM1

by October 18, 2001. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. on October 24, 2001, between approximately 2:45 p.m. and 3 p.m. on October 25, 2001, and between approximately 11:15 a.m. and 11:30 a.m. on October 26, 2001.

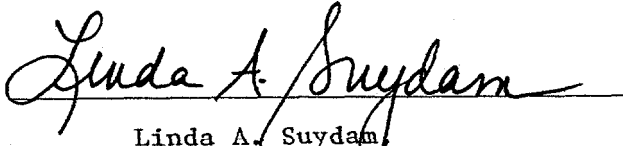
Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 18, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 9-21-01
September 21, 2001.


Linda A. Suydam
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

